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The safety and adequacy of device registries for endovascular aortic aneurysm repair: systematic review and meta-analysis

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Abstract

Objective

New stent grafts for endovascular aortic aneurysm repair (EVAR) are released regularly. Manufacturers and investigators publish registries to assess stent graft performance, but little is known about the adequacy of these to detect rates of clinically relevant complications. The aim of this study was to determine acceptable non-inferiority for EVAR stent grafts, then to determine the number of patients required for a new device registry to demonstrate it.

Methods

MEDLINE and EMBASE were searched for studies reporting outcomes of specific grafts, from inception to November 2016. Outcomes included endoleak, reintervention and late rupture rates. An expert consensus was performed to define non-inferiority. Meta regression was performed and a Bayesian approach was used to calculate patient numbers needed to achieve 80% power to detect a graft performance which was defined as acceptable by expert consensus at the 5% level. Analyses were adjusted for significant confounders.

Results

One hundred and forty-seven papers involving 27,058 patients were included. Mean follow-up was 24 months. Expert consensus defined non-inferiority for registries of new EVAR stent grafts as a better cumulative endoleak rate

(excluding type II) than the worst performing 25% of stent grafts. Estimated rates (\pm standard error) of overall endoleak (excluding type II) at 2 years was $5.7\pm0.6\%$. The number of patients who would need to be enrolled in a registry to prove non-inferiority with 2-year follow-up was calculated as 525 patients. Only two of the 147 studies included achieved this number of patients and duration of follow-up. Historical stent grafts varied significantly in performance.

Conclusions

Five hundred and twenty five patients need to be entered into a registry to prove non-inferiority to previous stent grafts. Published registries were inadequate, with only 1% of included studies achieving enough patients. With performance varying between devices, and the majority of grafts included in this analysis now being last generation, there is an urgent need to capture higher quality data on new EVAR stent grafts.

Introduction

The incidence of abdominal aortic aneurysm (AAA) repair continues to increase in the western world (1). Around 40,000 non-ruptured AAA are treated every year in the US alone, with 80% being treated endovascularly. In the UK the proportion of AAA treated endovascularly has increased from less than 10% in 2005 to around 60% in 2012, and continues to grow (1). An infrarenal stent graft for endovascular AAA repair (EVAR) costs around £7000 (2).

This creates a lucrative market for device manufacturers, and new stent grafts for performing EVAR are released regularly. Commonly used, established stent grafts are given regular iterative updates, which often retain the same name for marketing but may alter the graft design and structure (3,4). The 'safety' and marketing data for these devices is usually based on post-market surveillance registry publications; a recent Cochrane review highlighted that no randomised trials exist comparing one stent graft type with another (5). Stent graft fixation, material and stent design all vary between manufacturers, and different devices have appeared to suffer from different types of failure historically (6).

These device failures lead to a significant late complication rate after EVAR, which includes treated AAAs rupturing leading to death (7). Even though there is a perception that individual stent graft designs failed in different ways, these have results never been pooled and compared. The adequacy of stent graft registry publications to detect failures which could lead to patient death is unknown. Exactly which of these late failures is of most interest to surgeons and radiologists is also undefined. The aim of this paper

was therefore to define an acceptable non-inferiority limit for EVAR stent grafts, and to calculate the number of patients needed in a registry to prove non-inferiority to the performance of stent grafts in the literature.

Methods

Search methods

A systematic review of published work was conducted *as per* the protocol specified by the Cochrane collaboration (8), and reported in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement for the conduct of meta-analyses of intervention studies (9). The following sources were searched: Medline via PubMed, Embase and the Cochrane Library Database (Cochrane Central Register of Controlled Trials) for studies comparing stent graft types for endovascular repair of Abdominal Aortic Aneurysms (AAAs). All studies describing results from more than ten patients were included. Non-English language papers were excluded. Studies arising from duplicate publications were excluded. Review articles were excluded. Studies were excluded if the subjects included non-degenerative AAAs, thoracic, thoraco-abdominal or isolated iliac aneurysms. Studies of only emergency or complex aneurysms (fenestrated, extreme anatomy (e.g. angled neck, short neck)) were excluded, though if these were case cohort studies, data from the control group (non-emergency, non-complicated) were extracted. Studies of endovascular sealing devices were excluded. As a result, stent grafts (and manufacturers) included were: Zenith (Cook); Zenith Low Profile (Cook); Endurant (Medtronic); Excluder (Gore); AFX (Endologix); Anaconda (Vascutek); Aorfix (Lombard); Powerlink

(LeMaitre); Talent (Medtronic); AneuRx (Medtronic); Incraft (Cordis). For each stent graft the heading “Aneurysm” and the specific stent graft name e.g. “Excluder” were used as search terms.

Articles were also identified by hand searching of references and extensive use of the related articles function in PubMed. The last search date was 24th November 2016.

Data extraction

Data were extracted independently by two authors (FK and DB). Data extraction was initially trialled on 10 papers, and then refined. Extracted demographic data included: stent graft studied, company sponsored study, on or off label use, years over which graft studied, study design, number of patients and duration of follow up.

Outcome data collected included endoleak rates and types, reintervention rates, and late rupture rates. Data on type IV and V endoleaks were initially collected, but due to the extremely low reported rates of type IV leaks, and the heterogeneity inherent in type V leak definition, results for these types of leaks were not further examined, though they are pooled within total cumulative endoleak rates. Study quality was assessed using the Newcastle-Ottawa scale (10). Further details of extracted data are given in Appendix 1. Where short and long-term results from the same patient cohort were published separately, relevant data were retrieved from both publications preferentially using the latest.

Expert survey

No formal guidance exists to define adequacy and/or inferiority of endovascular devices. Numerous outcomes could potentially be selected when comparing new endografts with existing products. Furthermore, how non-inferiority should be defined (in terms of deviation from previously published outcome rates) has not previously been stipulated.

In order to decide how to define clinically significant failure rates for use in determining the appropriate sample size for a new device registry, we surveyed the medical members of the British Society for Endovascular Therapy (BSET) Council (<https://www.bset.co.uk/about-bset/council-members/>) for a consensus. The council includes high volume EVAR practitioners and actively publishing EVAR academics. The council were asked what statistical definition of non-inferiority should be used for a power calculation, and what they felt was the most relevant complication on which to base that calculation. The questionnaire was performed before any analyses. The full survey, with multiple choice options and answers, is given in Supplementary Table 1.

Statistical analysis

Type I-III endoleaks were modelled using weighted linear regression modelling, with constant term representing initial 'failure to seal' and linear term representing subsequent development of leak over time:

$$\text{Leak rate} = \text{Late leak rate} \times \text{mean follow-up time} + \text{failure to seal}$$

Terms were weighted in the regression analysis according to the number of patients in the study. Overall endoleak rates, reintervention rates and rupture rates were modelled in the same way. Negative 'failure to seal' estimates were set to zero. Confounder adjustment was performed using multivariate linear regression for mean patient age, proportion of male patients and mean aneurysm diameter if these terms were significant based on calculation of **Akaike's Information Criterion**. Separate regression models were also fitted for graft types with data from at least 10 studies.

Attrition rates for EVAR treated patients were needed to calculate numbers of patients required for entry into a registry to produce enough patients at 2 and 5 years to detect late complications. This length of time was chosen based on previous randomised data picking up the majority of early complications in this timeframe. Rates were calculated by pooling attrition rates for the EVAR arms of all randomised control trials on EVAR vs. open repair or conservative management for AAA (11-15), as these are likely to be more accurate than registry data.

A Bayesian approach was used to investigate the number of patients required in a registry for a new device to detect leak, reintervention or late rupture rates ('rates') which were inferior by a defined, 'clinically significant' quantity – determined by the expert survey. Rates were modelled using a Beta prior, with parameters estimated from the meta-regression above. A binary search strategy was then used to find the number of patients in the new registry which would be required to show inferior rates with 80% power if the new graft's rate was inferior by the pre-defined 'clinically relevant' amount and the registry was kept for 2 and 5 years. This was done by generating

100,000 draws from that distribution, calculating the proportion of times the estimate of the given parameter lay outside a 95% highest posterior density region of the accepted value, and then using this as our estimate of the power.

Results

Literature search and study characteristics

Database searches identified 1584 unique studies and searching through references revealed 17 further studies (Figure 1). A total of 1601 abstracts were screened and 213 full articles were obtained. 147 papers involving 27,058 patients were included in analysis. This included no randomised controlled trials, 22 registries/Phase II clinical trials, 46 cohort studies and 79 case series. 70 (48%) studies were prospective. The median Newcastle Ottawa score was 4 (range 3 to 8; supplementary table 2). 15% were company funded registries and 22% of remaining papers declared company sponsorship. 37% of studies included only patients treated according to the manufacturer's instructions for use (IFU) Full details of all included studies are given in supplementary table 1.

Weighted mean follow up was 24 months (range 1–120 months). The median patient number enrolled on the studies was 111 (interquartile range 49 to 214). The median patient number enrolled on company sponsored registries was larger at 236 (interquartile range 80 to 357), and **was significantly higher than non-company sponsored registries at Y (interquartile range X to Z) p=0..** The pooled mean patient age was 73 years, and 89% of patients were male. The mean aneurysm size was 57mm.

The weighted mean attrition rate at 30 days was 40%. By one year, attrition rates were 60%.

Expert survey

We received 13 responses from 16 polled experts. All of these responded to both questions. The majority (seven respondents) felt that a new device could be declared non-inferior if the registry were large enough to show with reasonable power that complication rates were definitely better than the worst performing 25% of existing grafts.

Regarding the most important outcome for calculating sample size, five respondents selected 'endoleak rate excluding type II endoleaks', four respondents selected 'reintervention rates', while two thought 'type I endoleak rate' was most important. Full results are given in Supplementary Table 1.

Endoleak rates

Table 1 shows pooled results from meta-regression after EVAR. Type I, II and III endoleak rates (\pm standard error) at 2 years were $3.4 \pm 0.3\%$, $13.0 \pm 1.0\%$ and $0.8 \pm 0.1\%$ respectively. The overall endoleak rate at 2 years was $18.9 \pm 1.2\%$, and was $5.7 \pm 0.6\%$ when type II endoleaks were excluded. Figure 2 shows the fitted regression model for overall endoleak rate (excluding type II) as well as data from the available studies.

The number of patients required for a registry to detect non-inferiority for total endoleak rate (excluding type II) was calculated as 436 patients at 2 years without adjusting for attrition. Taking attrition rates into account, the number of patients needing to be enrolled in order to achieve this number at

two years would be 525. Only two of the 147 studies published in the literature (16,17) had sufficient numbers of patients and duration of follow-up to satisfy the requirements of the expert survey.

Reintervention and rupture rates

The second most popular choice in the expert consensus was reintervention rates. This was $11.1 \pm 0.7\%$ at two years; $3.1 \pm 0.3\%$ of was for type II endoleaks. 492 patients would be required to detect non-inferiority for reintervention rates at 2 years. Figure 3 shows the fitted regression line for reintervention rates as well as data from the available studies.

Late rupture rates were $0.6 \pm 0.1\%$ at two years. Far larger numbers would be needed for a registry to detect late rupture rates; 2773 patients would need to be enrolled in order to show non-inferiority for this outcome at two years. None of the included studies enrolled patient numbers this large.

Graft-specific rates

Six grafts (Zenith, Talent, Endurant, Excluder, Anaconda and AneuRx) had data from at least 10 separate studies (23, 24, 23, 28, 10 and 21 respectively). Zenith could not be subdivided into Zenith and Zenith Low Profile (LP) because of the 23 studies (5754 patients) reporting on Zenith only one (18) included a cohort with Zenith LP (101 patients). Endurant could also not be subdivided in this way: of 25 studies (4783 patients), only one study reported outcomes from Endurant II (64 patients) (19), and there were no studies of the current Endurant IIs.

Predicted endoleak, reintervention and late rupture rates at 2 years for the different grafts are given in Table 2. Stent grafts did perform significantly differently. For example the Endurant graft from Medtronic performed significantly better for cumulative endoleak rate (excluding type II) than its predecessor the Talent graft, with rates of $3.5 \pm 1.2\%$ vs. $8.4 \pm 1.6\%$ ($p < 0.01$) respectively.

Discussion

This study has shown that 525 patients are required for a registry to show acceptable non-inferiority at 2 years for new or altered EVAR stent grafts. Only 2 of 147 studies in the literature meet this requirement (16,17). One was a company-sponsored registry (16). Both of these stent grafts have been subsequently redesigned to be mounted on low profile delivery devices, which means although they are marketed under similar names they differ in both stent and graft material design. Neither of the redesigns have publications with enough patients to satisfy our non-inferiority definition.

To put the primary outcome measure of non-inferiority into context, cumulative endoleak rate (excluding type II) means that all graft related failures (Type, I, III, IV and V endoleaks) are included. Type II endoleaks are thought to be patient related and therefore representative of patient selection rather than the stent graft itself (20). Type II endoleaks are also more variably detected and reported, intervened for, and are thought to be less clinically relevant than the others (21). This perception is reinforced by cumulative endoleak (excluding type II) having the best fit of all meta-regression models run (Table 1; adjusted R^2 0.28). The model fit improved significantly (0.09 to

0.28) when type II endoleak was removed, and the fit for type II endoleak reintervention was relatively poor (0.15). Stent graft limb occlusion rates could also be included a composite endpoint like this, however they are also variably reintervened for, and almost never lead to patient death. All endoleaks apart from type II can all lead to rupture and death if not treated.

Attrition rates were particularly high in these studies. This is first evident at 30 day follow up, with a 40% pooled attrition rate. This compares badly even to the EVAR 2 trial which included medically unfit patients and had attrition rates higher than RCT's of representative AAA patients (11). This is therefore likely to be poor follow up, and needs addressing in future registries. The late results of the EVAR 1 randomised trial, which randomised patients fit for open repair to either that or EVAR, has shown a significant late (>5 year) complication rate in the EVAR arm (7). Although stent graft design have changed in this time and complications reduced (Table 2), this remains a concern. Pragmatically, the cost of entering enough patients and maintaining registries this long makes it unlikely, but other data sources should be considered. For example, the National Vascular Registry in the UK captures data on all EVARs performed in the UK, and stent graft type could be easily added as a field (22). Registries can be powerful for detecting device related complications as shown by the metal on metal hip implant scandal which was first detected by the National Joint Registry of England and Wales (23,24). This is urgently required for EVAR stent grafts as different designs performed significantly differently from one another in our analysis when comparing graft related endoleaks.

Study quality was poor in this field which could be improved in the future by powering studies using the numbers in this analysis, better follow up regimes and improved data collection. There was also significant variability in outcome reporting between studies, so future datasets could be standardised using outcomes we have reported in this study. Aneurysm related survival could also be reported, but would need a huge number of patients to have any power and is difficult to collect outside a randomised control trial.

We wanted to analyse or adjust data by adherence to manufacturers IFU, but could not because of a lack of reporting within studies. This would have been interesting because adherence to the IFU is known to produce better clinical results (25). However in real world studies only 30% to 70% of stent grafts are actually inserted in anatomy adhering to IFU (26), so this analysis remains a valid, pragmatic representation of the use of stent grafts during EVAR. We also wanted to subdivide grafts by iterative updates under the same or similar name, however this was impossible because the current generation updated grafts had too little data available.

The definition of non-inferiority used was from an expert consensus, but we acknowledge that there are many other ways to define non-inferiority in this setting; there is no standard. For that reason, analyses are included which would allow other researchers to calculate patient numbers based on other definitions. The consensus was taken before analysis but examining the results the outcome chosen appears reasonable; the regression model fit was the best for this outcome and the number of patients needed to power sat between the lowest and highest for other outcomes.

Conclusion

Five hundred and twenty five patients need to be entered into a registry to prove non-inferiority to previous stent grafts for EVAR. Current registries are inadequate, with only 1% of included studies achieving enough patients. With performance varying between devices, and the majority of grafts included in this analysis now being last generation, there is an urgent need to capture higher quality data on EVAR stent grafts.

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Figure 1. Identification process for eligible studies

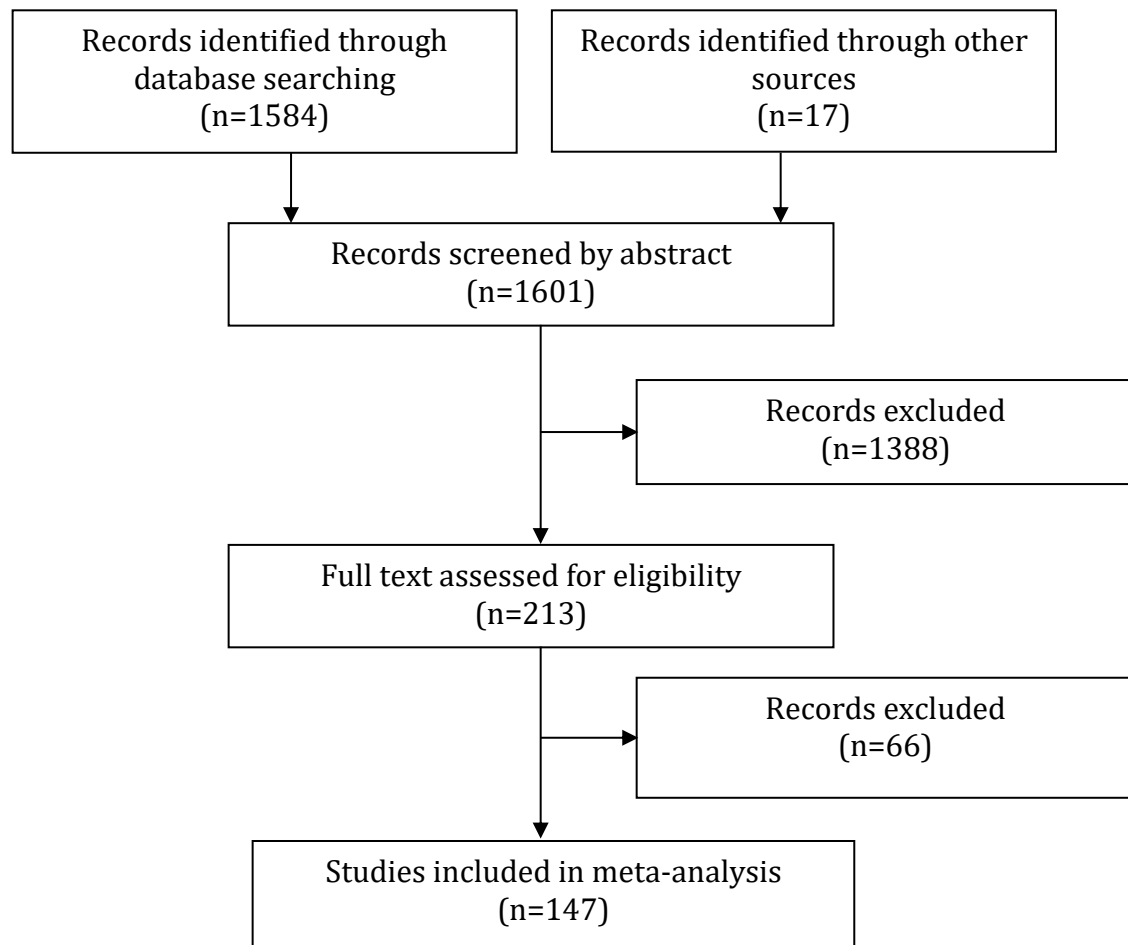


Figure 2. Bubble plot showing fitted meta-regression model for cumulative endoleak (excluding type II).

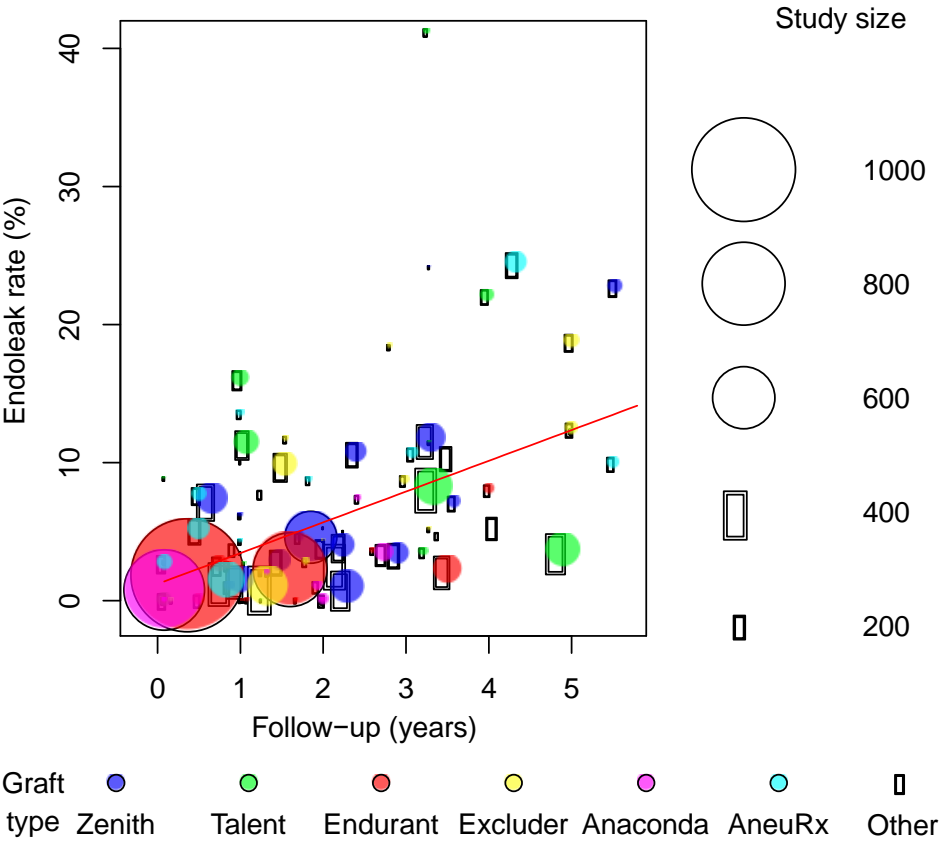


Figure 3. Bubble plot showing fitted meta-regression model for reintervention rate.

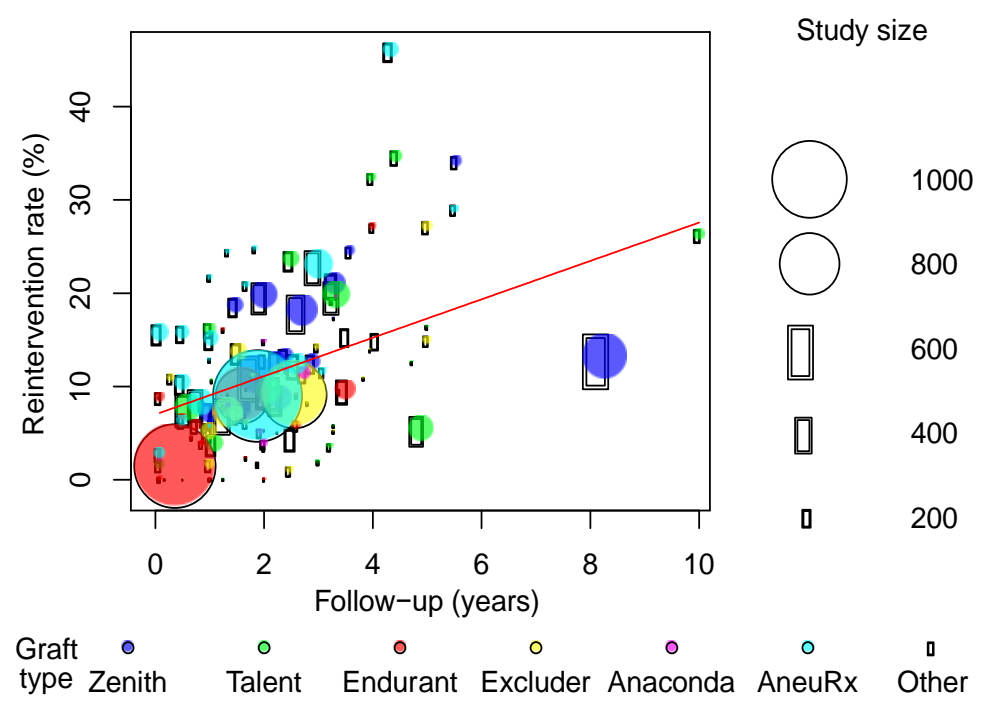


Table 1. Results of pooled meta-regression. Numbers in the final two columns are the number of patients needing to be entered into the registry to show non-inferiority for the stated outcome. Numbers needed to show non inferiority have been adjusted to allow for attrition rates similar to those seen in randomised controlled trials, which were 17% at 2 years and 41% at 5 years.

	Total no. of patients	Number of studies	Mean follow up time (yrs)	Estimated rate at two years follow-up (%)	Standard error	Adjusted R ²	Numbers needed to show non inferiority	
							2 years	5 years
Type I endoleak	17068	106	2.10	3.39	0.29	0.24	903	1190
Type II endoleak*	17900	110	1.84	13.04	0.96	0.04	298	278
Type III endoleak	16116	98	1.87	0.76	0.13	0.25	964	1597
Cumulative endoleak	16035	104	2.09	18.86	1.23	0.09	225	212
Cumulative endoleak rate excluding Type II	13636	89	1.88	5.67	0.55	0.28	525	720
Reintervention rate**	21595	126	2.26	11.12	0.68	0.23	492	500
Reintervention for Type II	15586	101	2.05	3.08	0.28	0.15	970	1273
Late rupture***	20999	100	2.13	0.60	0.07	0.20	2773	3759

* Adjusted for the proportion of male patients

**Adjusted for median patient age and mean aneurysm size

*** Adjusted for mean aneurysm size

Table 2. Graft-specific endoleak, re-intervention and late rupture rates for the six grafts with data from at least 10 studies.

	Type I endoleak	Type II endoleak	Type III endoleak	Cumulative endoleak	Cumulative endoleak rate excluding Type II	Reintervention rate	Reintervention for Type II	Late rupture
Zenith	3.5 ± 0.6	17.9 ± 1.8	0.9 ± 0.3	25.9 ± 2.8	5.7 ± 1.2	11.6 ± 1.8	4.7 ± 0.6	0.9 ± 0.2
Talent	5.3 ± 0.8	10.8 ± 2.1	1.1 ± 0.4	18.4 ± 3.5	8.4 ± 1.6	11.9 ± 1.7	2.3 ± 0.7	0.8 ± 0.2
Endurant 1	2.0 ± 0.6	11.3 ± 2.0	0.5 ± 0.3	11.7 ± 3.2	3.5 ± 1.2	9.5 ± 1.9	2.3 ± 0.6	0.3 ± 0.2
Excluder	2.5 ± 0.7	11.6 ± 2.1	0.1 ± 0.3	23.0 ± 3.9	7.0 ± 1.8	10.2 ± 1.8	3.1 ± 0.7	0.4 ± 0.2
Anaconda	2.2 ± 1.0	14.8 ± 3.0	0.5 ± 0.5	15.1 ± 4.1	3.4 ± 1.8	8.7 ± 3.5	0.8 ± 1.3	0.4 ± 0.3
AneuRx	6.1 ± 0.9	11.9 ± 2.4	2.4 ± 0.5	19.2 ± 3.7	8.7 ± 1.7	15.4 ± 1.5	4.2 ± 0.8	0.7 ± 0.2

Supplementary Table 1. Expert survey options and responses. The ‘other’ response to Question 1 was ‘I would be interested in superiority. Being no worse than others in the era of modern technology and generally low device failure rates just brings more of the same.’ The ‘other’ response to Question 2 was ‘Probably cumulative endoleak rate excl type II, unless the device is designed to prevent type IIs in which case then all endoleaks.’

Question	Responses
1. Which of the following do you think is most acceptable when evaluating non-inferiority for a new EVAR device?	
The registry is large enough to detect complication rates which are 50% higher than average	4
The registry is large enough to detect complication rates which are twice as high as average (i.e. 100% higher)	0
The registry is large enough to show that complication rates are better than the worst performing 25% of grafts on the market	7
The registry is large enough to show that complication rates are better than the worst performing 5% of grafts on the market	1
Other (please specify)	1
2. Which of the following outcomes to you think is the most important for power calculations when deciding how many patients to include in a device registry for a new infrarenal stent graft?	
Type I endoleak rate	2
Type II endoleak rate	0
Type III endoleak rate	0
Type IV endoleak rate	0
Type V endoleak rate	0
Cumulative endoleak rate	0
Cumulative endoleak rate excluding type II	5
Re-intervention rate	4

Late rupture rate	1
Other (please specify)	1

Supplementary table 2. Characteristics of included studies.

Paper	Company	Graft	Publication year	Study period	Study length (years)	Study type	Time of analysis	Company sponsored	On IFU?	Power calculation?	Number of patients	Mean age (years)	Sex (% male)	ASA ≥3 (%)	Median ASA	Aneurysm width (mm)	Ruptures included?	Follow up (years)	Newcastle Ottawa score
Abbruzzesse TA et al(27)	Cook	Zenith	2008	1999-2005	6	Cohort	Retrospective	No	No	No	177	76.0	85%	n.s	n.s	58.40	n.s	1.64	8
Abraham CZ et al (28)	Cook	Zenith	2002	1998-2001	3	Case series	Prospective	No	No	No	116	75.0	95%	65%	3	60.30	No	0.86	8
Alric P et al(29)	Cook	Zenith	2002	1996-2001	5	Case series	Prospective	No	Yes	No	88	72.6	95%	68%	3	66.00	No	1.71	8
Becquemin JP et al(30)	Cook	Zenith	2008	2000-2004	4	Case series	Prospective	No	n.s	No	212	72.9	95%	n.s	n.s	55.50	No	1.48	4
Bos WTJG et al(31)	Cook	Zenith	2008	1999-2006	7	Case series	Retrospective	No	No	No	234	72.1	92%	59%	3	60.90	No	2.24	4
D'Elia P et al(32)	Cook	Zenith	2009	2004-2008	4	Case series	Prospective	No	n.s	No	501	n.s	n.s	n.s	n.s	n.s	n.s	1.85	4
Greenberg RK et al(33)	Cook	Zenith	2001	1995-2001	6	Registry	Prospective	Yes	No	No	528	73.0	88%	66%	3	58.80	No	0.66	8
Haider S et al(34)	Cook	Zenith	2006	2002-2007	5	Cohort	Prospective	No	n.s	No	49	73.0	84%	n.s	n.s	52.10	No	1	8
Hager ES et al(35)	Cook	Zenith	2012	2002-2009	7	Cohort	Retrospective	No	No	No	24	74.8	88%	n.s	n.s	49.00	No	1.54	8
Hinchliffe RJ et al(36)	Cook	Zenith	2004	1996-2002	6	Registry	Retrospective	Yes	No	No	269	74.0	90%	70%	3	65.00	Yes (0.37%)	1	4
Hiramoto JS et al(37)	Cook	Zenith	2007	1998-2005	7	Case series	Prospective	No	n.a	No	325	75.9	92%	n.s	n.s	59.50	No	2.29	4
Iwakoshi S et al(38)	Cook	Zenith	2014	1999-2011	12	Case series	Retrospective	No	No	No	127	78.0	91%	n.s	n.s	49.00	No	3.58	4
Mertens J et al(39)	Cook	Zenith	2011	1998-2003	5	Case series	Prospective	No	No	No	143	71.3	94%	33%	2	57.50	No	5.53	4
Nevala T et al(40)	Cook	Zenith	2009	2001-2005	4	Case series	Retrospective	No	No	No	206	73.2	88%	n.s	n.s	62.00	No	2.4	4
Oberhuber A et al(41)	Cook	Zenith	2010	1998-2007	9	Cohort	Retrospective	No	No	No	29	71.0	90%	n.s	n.s	61.30	No	3.28	8
Ouriel K et al(42)	Cook	Zenith	2003	1996-2002	6	Cohort	Retrospective	No	Yes	No	325	75.0	86%	n.s	n.s	58.00	No	n.s	8
Sheehan MK et al(43)	Cook	Zenith	2006	1996-2003	7	Cohort	Retrospective	No	No	No	370	n.s	n.s	n.s	n.s	n.s	n.s	0.5	7
Sobocinski J et al(18)	Cook	Zenith	2015	2010-2013	3	Cohort	Retrospective	No	No	No	208	71.8	92%	97%	n.s	52.25	No	2.9	8
The EVAR Trial Participants et al(44)	Cook	Zenith	2007	2001-2005	4	Cohort	Retrospective	No	n.s	No	427	74.8	91%	n.s	n.s	65.02	No	2.7	8

Vaaramaki S et al(45)	Cook	Zenith	2012	2000-2010	10	Case series	Retrospective	No	No	No	282	75.0	88%	n.s	n.s	60.00	No	3.3	4
Verzini F et al(17)	Cook	Zenith	2016	2000-2011	11	Case series	Retrospective	No	No	No	610	73.2	93%	69%	3	55.53	No	8.27	4
Wales L et al(46)	Cook	Zenith	2008	2001-2007	6	Cohort	Prospective	No	No	No	153	73.5	91%	n.s	n.s	62.70	No	1.3	8
Zenith AAA Endovascular Graft Annual Clinical Update 2012(47)	Cook	Zenith	2012	2000-2005	5	Registry	Prospective	Yes	No	No	351	n.s	93%	n.s	n.s	n.s	No	n.s	4
Setacci F et al(48)	Medtronic	Endurant	2014	2010	1	Case series	Retrospective	No	Yes	No	137	76.1	77%	84%	n.s	65.50	No	0.08	8
Bisdas T et al(49)	Medtronic	Endurant	2014	2007-2010	3	Case series	Prospective	No	No	No	273	73.0	90%	n.s	n.s	57.00	No	3.5	4
Donas KP et al(50)	Medtronic	Endurant	2015	2007-2013	6	Case series	Prospective	No	No	No	712	73.4	89%	n.s	n.s	54.00	No	1.6	4
Garbo G et al(51)	Medtronic	Endurant	2014	n.s	n.s.	Cohort	Retrospective	No	n.s	No	22	74.3	n.s	n.s	n.s	51.00	n.s	1.87	8
Georgiadis GS et al(52)	Medtronic	Endurant	2011	2009-2010	1	Cohort	Prospective	No	Yes	No	43	70.2	100%	33%	n.s	58.70	No	1.08	8
Georgiadis GS et al(52)	Medtronic	Endurant	2011	2009-2010	1	Cohort	Retrospective	No	No	No	34	72.8	97%	56%	n.s	60.40	No	1.03	8
Goncalves FB et al(53)	Medtronic	Endurant	2011	2008-2009	1	Cohort	Retrospective	No	No	No	45	74.0	80%	73%	3	68.60	No	0.08	7
Goncalves FB et al(53)	Medtronic	Endurant	2011	2008-2009	1	Cohort	Retrospective	No	Yes	No	65	74.0	91%	66%	3	58.80	No	0.08	7
Hyhlik-Durr A et al(54)	Medtronic	Endurant	2011	2008-2009	1	Case series	Retrospective	No	No	No	50	75.0	98%	n.s	3	56.60	Yes (4%)	1.25	4
Kvinlaug KE et al(55)	Medtronic	Endurant	2012	2008-2010	1	Case series	Retrospective	No	No	No	111	75.0	81%	n.s	n.s	61.00	No	0.5	3
Makaroun MS et al(56)	Medtronic	Endurant	2011	2008-2009	1	Registry	Prospective	Yes	Yes	No	150	73.1	91%	n.s	n.s	57.00	No	0.92	4
Matsagkas M et al(57)	Medtronic	Endurant	2015	2008-2012	4	Cohort	Retrospective	No	No	No	19	71.7	84%	74%	3	57.00	No	2	8
Matsagkas M et al(57)	Medtronic	Endurant	2015	2008-2012	4	Cohort	Retrospective	No	Yes	No	38	71.6	90%	69%	3	58.00	No	2	8
Mensel B et al(58)	Medtronic	Endurant	2012	2007-2010	3	Cohort	Retrospective	No	No	No	36	78.6	94%	n.s	n.s	58.90	Yes (8.33%)	0.08	8
Mwipatayi BP et al(59)	Medtronic	Endurant	2013	2008-2011	3	Case series	Retrospective	No	Yes	No	44	75.0	91%	84%	3	57.00	No	1.67	8

Mwipatayi BP et al(59)	Medtronic	Endurant	2013	2008-2011	3	Case series	Retrospective	No	No	No	31	75.0	94%	71%	3	57.00	No	1.67	8
Pecoraro F et al(19)	Medtronic	Endurant	2016	2012-2015	3	Cohort	Retrospective	No	No	No	64	75.5	n.s	n.s	n.s	62.76	No	1.89	4
Rouwet EV et al(60)	Medtronic	Endurant	2011	2007-2008	1	Registry	Prospective	Yes	Yes	No	80	72.8	95%	34%	2	55.90	No	0.92	4
Stokmans RA et al(61)	Medtronic	Endurant	2012	2009-2013	4	Registry	Prospective	Yes	No	No	1262	73.1	90%	52%	3	60.30	No	0.08	3
Tang T et al(62)	Medtronic	Endurant	2013	2009-2010	2	Registry	Prospective	Yes	No	No	1089	73.1	90%	52%	3	n.s	No	0.36	4
Torsello G et al(63)	Medtronic	Endurant	2010	2007-2008	1	Case series	Retrospective	No	No	No	45	72.7	98%	69%	3	58.00	No	0.67	4
Troisi N et al(64)	Medtronic	Endurant	2010	2007-2009	2	Case series	Retrospective	No	No	No	156	73.6	91%	82%	3	57.30	Yes (1.92%)	0.75	3
Troisi N, Torsello G et al(65)	Medtronic	Endurant	2014	2007-2010	3	Cohort	Prospective	No	Yes	No	121	73.0	93%	83%	3	55.90	No	2.6	8
Troisi N, Torsello G et al(65)	Medtronic	Endurant	2014	2007-2010	3	Cohort	Prospective	No	No	No	56	75.3	86%	89%	3	59.00	No	2.6	8
Zandvoort HJA et al(66)	Medtronic	Endurant	2014	2007-2009	2	Case series	Prospective	No	No	No	100	74.0	88%	49%	2	58.00	No	4	4
Abbruzzesse TA et al(27)	Gore	Excluder	2008	1999-2005	6	Cohort	Retrospective	No	No	No	111	75.7	66%	n.s	n.s	54.30	No	0.29	8
Aburahma AF et al(67)	Gore	Excluder	2004	1999	1	Cohort	Prospective	No	Yes	No	17	73.0	82%	n.s	n.s	n.s	No	0.5	7
Bachoo P et al(68)	Gore	Excluder	2013	2010-2012	2	Registry	Prospective	Yes	No	No	68	73.9	87%	n.s	n.s	66.00	n.s	0.08	3
Bachoo P et al(68)	Gore	Excluder	2013	2010-2012	2	Registry	Prospective	Yes	Yes	No	331	73.9	87%	n.s	n.s	59.00	n.s	0.08	3
Bos WTJG et al(69)	Gore	Excluder	2009	n.s	n.s	Case series	Retrospective	No	Yes	No	92	70.4	88%	n.s	n.s	n.s	No	2.98	4
Cartes-Zumelzu F et al(70)	Gore	Excluder	2002	1997-2001	4	Case series	Prospective	No	Yes	No	72	74.0	92%	76%	3	55.00	No	1.79	4
Cho JS et al(71)	Gore	Excluder	2004	1999-2002	3	Case series	Prospective	No	n.s	No	50	73.0	70%	n.s	n.s	n.s	No	2.8	4
Curci JA et al(72)	Gore	Excluder	2007	n.s	n.s.	Registry	Retrospective	Yes	Yes	Yes	428	73.6	83%	79%	n.s	55.90	No	n.s	8
Garbo G et al(51)	Gore	Excluder	2014	n.s	n.s	Cohort	Retrospective	No	n.s	No	29	71.0	97%	n.s	2	48.00	n.s	3.95	8
Ghotbi R et al(73)	Gore	Excluder	2010	2006-2009	3	Case series	Retrospective	No	n.s	No	100	74.1	91%	84%	3	56.10	No	1.67	4

Goncalves FB, Jairam A et al(74)	Gore	Excluder	2012	2000-2007	7	Case series	Retrospective	No	Yes	No	144	71.6	88%	62%	3	60.00	Yes (4.86%)	5	4
Hager ES et al(35)	Gore	Excluder	2012	2002-2009	7	Cohort	Retrospective	No	No	No	60	76.6	67%	n.s	n.s	58.00	No	1.55	8
Haider S et al(34)	Gore	Excluder	2006	2002-2007	5	Cohort	Retrospective	No	n.s	No	132	73.8	79%	n.s	n.s	n.s	No	1	8
Hogg ME et al(75)	Gore	Excluder	2011	2004-2007	3	Case series	Prospective	No	n.s	No	301	73.6	76%	n.s	n.s	51.80	No	1	4
Katsargyris A et al(76)	Gore	Excluder	2014	2010-2015	5	Case series	Prospective	No	No	No	200	72.4	88%	42%	2	57.00	Yes (3.5%)	1.48	4
Leurs LJ et al(77)	Gore	Excluder	2004	1998-2004	6	Registry	Prospective	Yes	n.s	No	676	72.0	93%	53%	3	56.76	n.s	1.13	4
Maleux G et al(78)	Gore	Excluder	2012	1998-2010	12	Case series	Retrospective	No	No	No	121	72.8	97%	41%	2	58.07	No	5	4
Mateo MMH et al(79)	Gore	Excluder	2016	2000-2014	14	Cohort	Retrospective	No	No	No	249	74.3	97%	n.s	n.s	56.86	n.s	2.54	8
Matsumura JS et al(80)	Gore	Excluder	2003	1998-2000	2	Registry	Prospective	Yes	Yes	Yes	235	73.0	87%	n.s	n.s	55.60	No	1.54	8
Melissano G et al(81)	Gore	Excluder	2005	1999-2005	6	Case series	Prospective	No	Yes	No	109	72.3	89%	79%	3	50.70	No	2.47	4
Oberhuber A et al(41)	Gore	Excluder	2010	1998-2007	9	Cohort	Retrospective	No	n.s	No	39	71.9	97%	n.s	n.s	57.60	No	3.28	8
Pfammatter T et al(82)	Gore	Excluder	2002	1998-2000	2	Case series	Prospective	No	No	No	66	70.0	85%	94%	3	56.00	No	0.48	4
Pratesi C et al(83)	Gore	Excluder	2014	1998-2006	8	Case series	Retrospective	No	Yes	No	872	72.7	92%	59%	3	52.40	No	2.55	4
Rhee RY et al(84)	Gore	Excluder	2003	1996-1999	3	Case series	Prospective	No	Yes	No	38	74.6	79%	n.s	n.s	50.00	No	1.33	7
Sheehan MK et al(43)	Gore	Excluder	2006	1996-2003	7	Cohort	Retrospective	No	n.s	No	111	n.s	n.s	n.s	n.s	n.s	n.s	2	7
Smeds MR et al(85)	Gore	Excluder	2013	2010-2011	1	Cohort	Retrospective	No	No	No	44	n.s	75%	n.s	n.s	59.00	No	0.17	7
The EVAR Trial Participants et al(44)	Gore	Excluder	2007	2004-2007	3	Cohort	Retrospective	No	n.s	No	37	73.4	84%	n.s	n.s	64.00	No	3.83	8
van der Laan MJ et al(86)	Gore	Excluder	2003	1999	1	Case series	Retrospective	No	n.s	No	23	n.s	n.s	n.s	n.s	n.s	No	2	7
Verhoeven ELG et al(87)	Gore	Excluder	2014	2010-2012	2	Registry	Prospective	Yes	No	No	400	73.9	87%	63%	3	59.90	Yes (1.5%)	1.33	4
Melas N et al(88)	Endologix	AFX	2015	2013-2014	1	Case series	Prospective	No	Yes	No	21	71.0	100 %	n.s	n.s	59.00	No	0.08	3

Welborn MB et al(89)	Endologix	AFX	2014	2011-2013	2	Case series	Retrospective	Yes	No	No	108	n.s	74%	88%	3	50.00	Yes (4.63%)	0.92	4
Freyrie A et al(90)	Vascutek	Anaconda	2007	2005-2006	1	Case series	Prospective	No	Yes	No	49	73.3	90%	92%	3	56.00	No	0.08	3
Freyrie A, Gallitto E et al(91)	Vascutek	Anaconda	2014	2005-2012	7	Case series	Prospective	No	Yes	No	177	73.3	94%	94%	3	55.00	No	2.74	4
Freyrie A, Gargiulo M et al (92)	Vascutek	Anaconda	2011	2009-2011	2	Registry	Retrospective	Yes	Yes	No	787	76.6	92%	81%	3	55.73	n.s	0.08	3
Karkos CD et al(93)	Vascutek	Anaconda	2015	2007-2014	7	Case series	Retrospective	No	Yes	No	68	71.0	97%	n.s	n.s	59.50	No	2.42	4
Majumder B et al(94)	Vascutek	Anaconda	2012	2005-2009	4	Case series	Prospective	n.s	Yes	No	106	77.0	85%	94%	3	63.00	n.s	2	4
Rodel SGJ et al(95)	Vascutek	Anaconda	2014	2005-2011	6	Case series	Prospective	Yes	No	No	36	74.0	83%	17%	2	71.00	No	3.33	4
Rodel SGJ, Geelkerken RH et al(96)	Vascutek	Anaconda	2009	2002-2005	3	Case series	Prospective	No	Yes	No	61	71.0	98%	33%	2	57.00	No	2	4
Saratzis N et al(97)	Vascutek	Anaconda	2008	2006-2007	1	Case series	Retrospective	No	Yes	No	51	71.0	94%	n.s	n.s	58.60	No	1.33	4
Stehr A et al(98)	Vascutek	Anaconda	2007	2003-2006	3	Case series	Prospective	No	Yes	No	14	72.2	86%	n.s	n.s	56.70	n.s	2	4
Stella A et al(99)	Vascutek	Anaconda	2009	2005-2008	3	Case series	Prospective	no	No	No	100	73.9	94%	93%	n.s	55.20	Yes (0.5%)	1.93	4
Albertini JN et al(100)	Lombard	Aorfix	2006	2002-2006	4	Case series	Retrospective	No	No	No	29	75.0	n.s	n.s	n.s	66.00	Yes (3.45%)	1	4
Balasubramaniam K et al(101)	Lombard	Aorfix	2009	2006-2009	3	Case series	Retrospective	No	Yes	No	40	77.5	98%	n.s	n.s	73.00	No	1	4
Hinchliffe RJ, Macierewicz et al(102)	Lombard	Aorfix	2004	n.s	n.s	Case series	Prospective	No	No	No	24	67.5	96%	38%	2	55.10	n.s	0.17	4
Perdikides T et al(103)	Lombard	Aorfix	2009	2005-2009	4	Case series	Prospective	No	Yes	No	20	72.4	100 %	45%	2	61.80	No	2.24	4
Sbarzagli P et al(104)	Lombard	Aorfix	2014	2009-2013	4	Case series	Retrospective	No	Yes	No	27	70.0	100 %	n.s	n.s	55.00	n.s	2.33	4
Weale AR et al(105)	Lombard	Aorfix	2011	2006-2008	2	Case series	Prospective	Yes	No	No	30	77.4	77%	57%	3	69.30	No	1	4
Albertini JN, Lahlou Z et al(106)	Endologix	Powerlink	2005	2000-2001	1	Case series	Prospective	No	Yes	No	64	70.0	95%	45%	2	55.00	No	3.38	4
Carpenter JP et al(107)	Endologix	Powerlink	2010	2000-2008	8	Case series	Prospective	No	No	No	157	72.0	90%	n.s	n.s	56.00	No	2	4

Coppi G et al(108)	Endologix	Powerlink	2008	1999-2007	8	Cohort	Retrospective	No	No	No	205	74.0	94%	58%	3	53.78	No	3.53	7
Jordon WD et al(109)	Endologix	Powerlink	2009	2005-2006	1	Registry	Prospective	Yes	Yes	Yes	78	73.0	91%	n.s	n.s	57.00	No	1.25	4
Qu L et al(110)	Endologix	Powerlink	2007	1999-2006	7	Case series	Prospective	n.s	No	No	378	69.3	86%	n.s	n.s	54.00	No	2.23	4
Wang GJ et al(111)	Endologix	Powerlink	2008	2000-2003	3	Registry	Prospective	Yes	Yes	Yes	192	73.0	88%	n.s	n.s	51.00	No	4.08	8
Cao P et al(112)	Medtronic	Talent	2009	2002-2006	4	Case series	Retrospective	Yes	No	No	349	73.8	90%	n.s	n.s	56.00	No	2.08	4
Chaven A et al(113)	Medtronic	Talent	2000	1997-1999	2	Case series	Prospective	No	Yes	No	22	66.8	100%	14%	2	27.00	No	1.33	4
Coppi G, Silingardi R, Saitta G et al(114)	Medtronic	Talent	2008	1997-2001	4	Case series	Retrospective	No	Yes	No	50	72.0	98%	58%	3	58.00	n.s	5	4
Cowie AG et al(115)	Medtronic	Talent	2003	1998-1999	1	Case series	Prospective	No	Yes	No	38	69.2	92%	68%	3	60.00	Yes (2.63%)	1.04	4
Criado FJ et al(116)	Medtronic	Talent	2003	1999-2000	1	Registry	Prospective	Yes	No	No	240	75.5	90%	1%	1	56.70	No	1.08	7
Dalainas I et al(117)	Medtronic	Talent	2007	2000-2003	3	Cohort	Prospective	No	Yes	No	87	n.s	n.s	100%	3	64.60	No	3.21	8
England A et al(118)	Medtronic	Talent	2004	1998-2001	3	Case series	Retrospective	Yes	n.s	No	55	72.0	93%	76%	3	63.20	Yes (1.82%)	3	4
Espinosa G et al(119)	Medtronic	Talent	2009	1997-2007	10	Case series	Prospective	No	No	No	337	72.5	84%	32%	2	59.00	No	4.89	4
Espinosa G, Marchiori A et al(120)	Medtronic	Talent	2002	1997-2001	4	Case series	Prospective	No	No	No	134	70.7	89%	44%	2	55.70	No	0.08	3
Faries PL et al(121)	Medtronic	Talent	2002	1999-2001	2	Case series	Prospective	Yes	n.s	No	368	75.8	85%	n.s	n.s	62.00	n.s	0.61	4
Garbo G et al(51)	Medtronic	Talent	2014	n.s	n.s	Cohort	Retrospective	No	n.s	No	40	71.8	97%	75%	3	51.00	n.s	4.72	8
Hausegger KA et al(122)	Medtronic	Talent	1999	1996-1997	1	Case series	Prospective	No	Yes	No	30	70.5	93%	90%	3	56.00	No	1.25	4
Mannetje YW et al(123)	Medtronic	Talent	2016	1999-2005	6	Case series	Retrospective	No	n.s	No	149	70.2	92%	35%	2	59.00	No	10	4
Mensel B et al(124)	Medtronic	Talent	2012	2007-2010	3	Cohort	Retrospective	No	No	No	35	75.0	94%	n.s	n.s	52.80	Yes (8.57%)	0.08	8
Oberhuber A et al(41)	Medtronic	Talent	2010	1998-2007	9	Cohort	Retrospective	No	n.s	No	35	69.6	91%	n.s	n.s	53.80	No	3.28	8

Ouriel K et al(42)	Medtronic	Talent	2003	1996-2002	6	Cohort	Retrospective	No	Yes	No	39	75.0	86%	n.s	n.s	58.00	No	n.s	8
Pitton MB et al(125)	Medtronic	Talent	2009	1997-2007	10	Case series	Prospective	No	Yes	No	128	73.0	90%	n.s	n.s	59.60	No	3.98	4
Seriki DM et al(126)	Medtronic	Talent	2006	1998-2002	4	Case series	Prospective	No	Yes	No	68	71.4	91%	75%	3	63.00	Yes (1.47%)	3.25	8
Sheehan MK et al(128)	Medtronic	Talent	2006	1996-2003	7	Cohort	Retrospective	No	n.s	No	182	n.s	n.s	n.s	n.s	n.s	n.s	3	7
The EVAR Trial Participants et al(44)	Medtronic	Talent	2007	2004-2006	3	Cohort	Retrospective	No	n.s	No	221	74.1	89%	n.s	n.s	64.58	No	2.5	8
Torsell G, Osada N et al(127)	Medtronic	Talent	2006	1996-1998	2	Case series	Retrospective	No	No	No	165	69.2	98%	73%	3	55.90	n.s	4.43	4
Turnbull IC et al(128)	Medtronic	Talent	2010	2002-2003	1	Cohort	Prospective	No	No	No	166	74.1	92%	n.s	n.s	55.00	No	1	8
Verhoeven BAN et al(129)	Medtronic	Talent	2011	2000-2007	7	Case series	Prospective	No	No	No	365	74.0	88%	74%	3	61.00	No	3.33	4
Wales L et al(46)	Medtronic	Talent	2008	2001-2007	6	Cohort	Prospective	No	No	No	133	73.2	90%	n.s	n.s	61.50	No	1.33	8
Torsello G, Scheinert D et al(130)	Cordis	InCraft	2015	2010-2011	1	Registry	Prospective	Yes	Yes	No	60	74.5	95%	n.s	n.s	52.60	No	2	4
Abbruzzesse TA et al(27)	Medtronic	Aneurx	2008	1999-2007	8	Cohort	Retrospective	No	No	No	277	76.6	82%	n.s	n.s	55.30	No	2.6	8
Arko FR et al(131)	Medtronic	Aneurx	2002	1996-2003	7	Cohort	Retrospective	No	n.s	No	200	73.6	83%	n.s	n.s	57.60	n.s	1.03	8
Arko FR, Lee A et al(132)	Medtronic	Aneurx	2001	1996-1998	2	Cohort	Retrospective	No	Yes	No	70	73.9	n.s	n.s	n.s	57.55	n.s	1.83	8
Ayerdi J et al(133)	Medtronic	Aneurx	2003	1999-2001	2	Registry	Retrospective	No	Yes	No	54	73.0	93%	n.s	n.s	52.00	No	1	8
Biasi GM et al(134)	Medtronic	Aneurx	1998	1996-1997	1	Case series	Prospective	Yes	Yes	No	100	70.8	91%	n.s	n.s	64.00	No	n.s	4
Hill BB et al(135)	Medtronic	Aneurx	2002	1995-1998	3	Cohort	Retrospective	No	Yes	No	79	74.0	86%	n.s	n.s	59.20	No	1.33	8
Hovsepian DM et al(136)	Medtronic	Aneurx	2001	1999-2000	1	Case series	Prospective	No	Yes	No	144	72.0	84%	n.s	n.s	56.00	No	0.5	4
Howell MH et al(137)	Medtronic	Aneurx	2001	1998-2001	3	Case series	Retrospective	No	n.a	No	215	72.0	89%	59%	4	55.50	No	0.5	4
Lee WA et al(138)	Medtronic	Aneurx	2002	1996-2000	4	Case series	Retrospective	No	Yes	No	150	74.5	87%	n.s	n.s	57.80	n.s	0.08	3

Martin EC et al(139)	Medtronic	Aneurx	2011	n.s	n.s.	Case series	Retrospective	No	n.s	No	121	71.0	89%	n.s	n.s	53.00	n.s	5.5	4
Nolthenius RPT et al(140)	Medtronic	Aneurx	2001	1996-2000	4	Case series	Prospective	No	Yes	No	77	70.0	97%	46%	2	n.s	n.s	1	4
Ramaiah VG et al(141)	Medtronic	Aneurx	2002	1999-2001	2	Case series	Retrospective	No	No	No	230	74.0	95%	92%	3	n.s	n.s	0.08	3
Ricco JB et al(142)	Medtronic	Aneurx	2002	1998-1999	1	Case series	Prospective	Yes	Yes	No	47	72.2	98%	28%	2	52.00	No	1	4
Sheehan MK et al(43)	Medtronic	Aneurx	2006	1996-2003	7	Cohort	Retrospective	No	n.s	No	444	n.s	n.s	n.s	n.s	n.s	n.s	1.5	7
Smith S et al(143)	Medtronic	Aneurx	2008	1999-2003	4	Case series	Retrospective	No	n.s	No	113	73.8	95%	n.s	n.s	57.00	n.s	3.08	4
Tonnessen BH et al(144)	Medtronic	Aneurx	2005	1997-2001	4	Cohort	Retrospective	No	n.s	No	105	73.0	90%	95%	3	55.30	No	1.67	8
van Herwaarden JA et al(145)	Medtronic	Aneurx	2007	1996-2003	7	Case series	Retrospective	No	Yes	No	212	71.3	93%	46%	2	59.10	No	4.33	4
Zarins CK et al(146)	Medtronic	Aneurx	1999	1996-1997	1	Registry	Prospective	Yes	Yes	No	190	73.0	90%	91%	3	56.00	No	0.5	8
Zarins CK, Bloch DA et al(147)	Medtronic	Aneurx	2004	1997-1998	1	Case series	Retrospective	No	No	No	383	73.0	89%	n.s	n.s	57.00	n.s	3	4
Zarins CK, Shaver DM et al(148)	Medtronic	Aneurx	2002	1999-2001	2	Cohort	Prospective	Yes	n.s	No	357	74.0	89%	n.s	n.s	56.40	n.s	0.83	8
Zarins CK, White RA et al(16)	Medtronic	Aneurx	2001	1996-1999	3	Registry	Prospective	Yes	Yes	No	1192	73.4	89%	92%	n.s	56.00	No	1.88	4

Appendix 1.

Study design	Cohort and graft characteristics	Baseline demographics and patient factors (Number of patients unless stated)	Outcomes (Number of patients unless stated)
Type of study (RCT / cohort / case series)	Number of patients	Age (median / mean)	Length of procedure in minutes (mean/median)
Data analysis (retrospective / prospective)	Graft type	Sex	Endoleak rate (separate for each type1-3)
Company sponsored (yes/no)	Company	ASA (median)	Total endoleak rate
Publication year	Graft generation	Aneurysm width	Total re-intervention rates
Midpoint of study year	Graft used on IFU (yes/no)	Follow up time (mean/median)	Late rupture rate
Ruptures included (yes/no)			
Newcastle-Ottawa score			